K021274

MAY 17 2002

ATTACHMENT 6

SMDA INFORMATION

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:

Vicki L. Drews
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, IL 60073

Date of Submission:

April 19, 2002

Proposed Device(s):

Baxter Dual Port Infusor
Baxter Pain Mate™ Pain Management System (Convenience Kits containing the Baxter Dual Port Infusor)

Comparison Device(s):

Infusor SV and LV Elastomeric Infusion Device

Description of Device(s):

The dual port line of Infusors are a modification of Baxter's currently marketed Infusor line of elastomeric infusion devices. The modification consists of adding a "Y" fitting and an additional section of administration set tubing resulting in a bifurcated tubing. This allows solution flow through two ports. There are no new materials or technology associated with the modification. In all other respects, the dual port Infusors are identical to Baxter's current Infusor SV and LV elastomeric pumps. Furthermore, the range of flow rates through each single port as well as through both ports combined, is within the current range of flow rates available in the single port Infusor devices.

Indications for Use:

The Dual Port Infusor is indicated for the slow, continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management.

Technological Characteristics:

The technological characteristics of the Dual Port Infusor are identical to those of the Infusor SV and Infusor LV devices. The Dual Port Infusor incorporates a bifurcated tubing to allow for solution flow through two ports.

A contraindication has been added to the labeling of the Pain-Mate Pain Management Systems with dual port Infusors. The Dual Port Infusor devices are contraindicated for intravenous, intra-arterial, and epidural use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2002

Ms. Vicki L. Drews
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I. V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Re: K021274
Trade/Device Name: Baxter Dual Port Infusor
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Unclassified
Product Code: MEB
Dated: April 19, 2002
Received: April 22, 2002

Dear Ms. Drews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

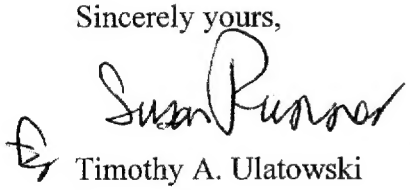
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021274

ATTACHMENT 8

INDICATIONS FOR USE

The Dual Port Infusor line of elastomeric pumps is indicated for the slow, continuous infusion of medications directly into an intraoperative site or subcutaneously for postoperative pain management.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021274